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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 3559 10/735,683 12/15/2003 Jane M. Hyman JH-1-gw **EXAMINER** 12/17/2004 Michael I. Kroll MOHANDESI, JILA M 171 Stillwell Lane ART UNIT PAPER NUMBER Syosset, NY 11791 3728

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,683	HYMAN, JANE M.	
	Examiner	Art Unit	
	Jila M Mohandesi	3728	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status .			
1) Responsive to communication(s) filed on <u>15 December 2003</u> .			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
4) ☐ Claim(s) 1-14 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-14 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement.			
Application Papers			
 9) ☐ The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 15 December 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 			
Priority under 35 U.S.C. § 119			
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 			
Attachment(s)	,		
Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)	
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da		
B) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	6) Other:	atent Application (FTO-152)	

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DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means", "comprised" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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4. Claims 11-14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Niada (EP 397 607) herein after Niada. Niada discloses a portable insulin and accessory kit, comprising: a box (half-box member 1), said box being substantially rectangular, said box having a top, bottom, front, rear, pair of opposing ends, and an inside and outside; a cover (upper member 2) being disposed on said top of said box, said cover having hinges for being hingedly attached to said box, said hinges being disposed on said rear of said box, a fastener (snap 8, 8a) being disposed on said front of said box for removably securing said cover to said box; a plurality of sections (11, 11a, 11b) being disposed internal said box to permit articles to be separately stored in said sections; an insulin source (insulin vial/syringe and what is needed to inject this substance) being disposed in one of said sections; at least one disinfectant pad (alcohol pads) being disposed in one said sections; a plurality of spare needles being disposed in a plurality of said sections to permit at least three needles to be disposed in the kit. See Figure 1 embodiment.

Although not specifically pointed out in the above reference, it is well know in the art that in order to inject the insulin to the diabetics, needles are needed and a clean needle should be used each time. Therefore it would be a safe assumption that the syringe of the above reference is provide with needles for injection of the substance to the diabetics. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide needles for use with the syringe for injection of the substance to the diabetics.

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Official notice is taken that it is old and conventional to make insulin syringes as insulin pens to make the process of self-injection easier to manage. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide insulin pens in lieu of the syringes in the diabetic kit of Niada.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5. Eitel (Des. 338,781) herein after Eitel in view of Niada. Eitel discloses a portable insulin and accessory kit, comprising: a flexible case, said case being substantially rectangular, said case being substantially planar, said case having an opposing first and second end, and opposing first and second side, and an inside and outside; said case having first, second and third substantially equal sections, wherein said first section is disposed toward said first end, said third section is disposed toward said second end and said second section is disposed between said first and third section, wherein said third section folds toward said first end over and contiguous to said second section, wherein said first section then folds over said third section so as to position said inside of said third section contiguous to said inside of said second section and said inside of said first section folds contiguous to said outside of said third section; at least one pocket disposed on said inside of each said first and third sections to permit an article to placed thereon; at least one receptacle being disposed on said inside of said second section to permit an article to be placed therein, and a fastener being disposed on said case to secure said case in said folded position. Diabetic kit of Eitel does not specifically disclosed what is stored therein. Niada discloses a portable diabetic kit including insulin sources, syringe/needles and disinfectant pads. Therefore, it would have been obvious

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to one of ordinary skill in the art at the time the invention was made to provide insulin sources/syringes and needles and disinfectant pads in the diabetic kit of Eitel as taught by Niada to properly accommodate a diabetic.

From Figure 8, it appears that the pockets are made of clear material, however if there is any doubt that the material is clear, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

With respect to claim 5, note the two pockets disposed on said inside of said third section to receive an article therein shown in Figure 9 embodiment.

With respect to claim 8, it appears that the fastener is made of hook and loop material furthermore, whether the fastener is hook and loop material or any other art recognized equivalent is an obvious matter of choice, such as to require less manual dexterity to operate.

With respect to claim 7, it appears that the receptacle is made of an elastic material, furthermore, whether the receptacle is made of elastic material or any other art recognized equivalent is an obvious matter of choice, such as to require less manual dexterity to operate.

Official notice is taken that it is old and conventional to make insulin syringes as insulin pens to make the process of self-injection easier to manage. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide insulin pens in lieu of the syringes in the diabetic kit of Eitel.

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Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shown are insulin kits analogous to applicant's instant invention.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jila M Mohandesi whose telephone number is (571) 272-4558. The examiner can normally be reached on Monday-Friday 7:30-4:00 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JILA M. MOHANDESI-PRIMARY EXAMINER

Jila M Mohandesi Primary Examiner Art Unit 3728

JMM December 02, 2004